

JUN - 2 2011

Attachment D: 510(k) Summary

Alara T210 Computed Radiography System

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter: Alara, Inc.
47505 Seabridge Drive
Fremont, CA 94538

Contact Person: Christopher R. Mitchell
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Date Prepared: August 5, 2010

Trade Name: Alara T210 Computed Radiography System

Common Name: Computed Radiography (CR) System

Classification Name: Solid State X-Ray Imager (per 21 CFR 892.1650)

Predicate Device: CRystalView T-Series Computed Radiography System (510(k)
No. K071682, August 15, 2007)

Product Description:

The Alara T210 is a desktop Computed Radiography (CR) system designed to generate digital x-ray images by reading photostimulable phosphor imaging plates exposed using standard x-ray systems and techniques. The system consists of a CR reader, imaging plates, and cassettes. A computer workstation and QC Acquisition software will be optionally provided by either Alara or the distribution channel.

Indications for Use:

The T210 Computed Radiography System is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film-screen systems in all general-purpose diagnostic procedures. The T210 is not indicated for use in mammography.

Rationale for Substantial Equivalence:

The T210 Computed Radiography System is a modification of the predicate device. It has the same indications for use as the predicate device. It has the same technological characteristics as the predicate device, including using the same optical subassembly. The

change in image size and system form factor resulted in Alara's decision to conduct substantial equivalence testing through verification and image quality performance testing. The results of this testing demonstrate that the T210 is substantially equivalent to the predicate device.

Safety and Effectiveness Information:

The T210 is a Class II medical device and a Class I laser product. It complies with applicable FDA and international standards pertaining to electrical, mechanical, EMC, and laser safety of medical and/or laser devices.

Alara has performed laboratory studies comparing the T210's performance characteristics to those for the predicate device.

Conclusion:

Performance testing of the Alara T210 Computed Radiography system has demonstrated that it is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Christopher Mitchell
Chief Scientific Officer
Alara, Inc.
47505 Seabridge Drive
FREMONT CA 94538

AUG 23 2013

Re: K102479

Trade/Device Name: Alara T210 Computed Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 22, 2011
Received: March 24, 2011

Dear Mr. Mitchell:

This letter corrects our substantially equivalent letter of June 2, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

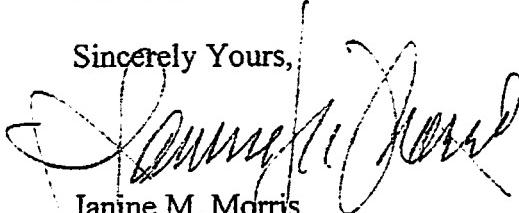
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Attachment B: Indications for Use Statement

510(k) Number: _____

Device Name: Alara T210 Computed Radiography System

Indications for Use: The Alara T210 Computed Radiography System is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film-screen systems in all general-purpose diagnostic procedures. The T210 is not indicated for use in mammography.

Mary S. Fad
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102479